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14. ABSTRACT
This award was for a Collaborative Agreement between Army Research Laboratory and the University of Minnesota for the further development of an Airway Part Task Trainer. The goal of the development project was to create a family of training systems with multiple levels of sophistication ranging from an inexpensive manual trainer to a fully instrumented, sensored system with feedback. The Cooperative Agreement fostered this development and provided for expansion of the project to address other options for the development of a modular, provider customized airway trainer.

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Center for Research in Education and Simulation Technologies
UNIVERSITY OF MINNESOTA
Driven to Discover℠

Final Report
Award # W911NF-13-2-0033

Development of a Modular, Provider Customized Airway Trainer

Effective Dates: 03 September 2013 – 25 September 2015

Report Date: 25 November 2015

Principal Investigator: Robert Sweet, MD
University of Minnesota Medical School

Cooperative Agreement Manager: Jack Norfleet (ARL)

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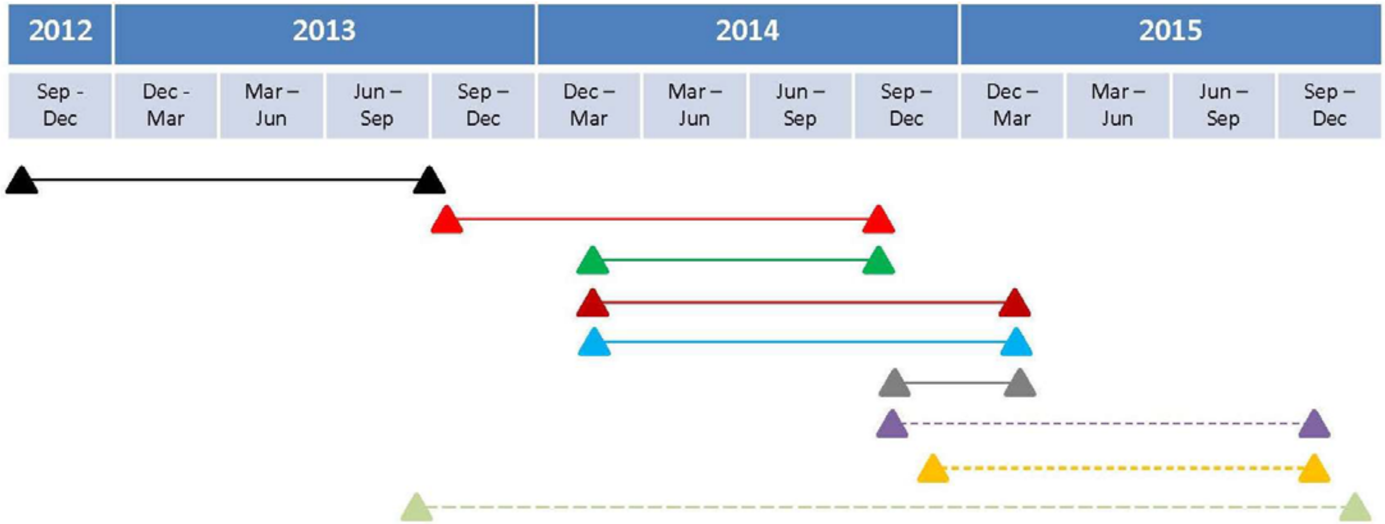
1 Airway Project Timeline



- Airway Part Task Trainer (Airway I) - $249,972 - Awarded 9/10/2012 - Prototype delivered 9/2013
- Development of a Modular, Provider Customized Airway Trainer (Airway II)- $264,961 - Prototype delivered 9/2014
  - Option 1: Validation Study - $28,686 - exercised 1/22/14 - completed 11/2014
  - Option 4b: Integrated Sensors for cric module - $84,756 - exercised 1/22/14, delivered 11/2014
  - Option 5: Pathologies - $136,299 - exercised 1/22/14, delivered 3/2015
  - Option 2: Additional Prototype - $40,938 - exercised 9/18/14, delivered 3/2015
  - Option 6: Connect to learning management system - $153,512 - exercised 9/18/2014, delivered 9/2015
  - Option 4e: Integrated Tissue Hydration - $84,756 - exercised 11/12/2014, delivered 9/2015
- Commercialization - by 7-Sigma

A total of 5 prototypes have been delivered for this project, and the original Airway I prototype has been remanufactured.

2 Executive Summary

This is the final report for the Development of a Modular, Provider Customized Airway Trainer Award # W911NF-13-2-0033, for

- CLIN 0001: Base project for improvement of Airway Trainer Prototype
- CLIN 0002: Option 1 Validation study, Option 4B Integrated sensors for cricothyrotomy, and Option 5 Pathologies
- CLIN 0003: Option 2 Additional prototypes
- CLIN 0004: Option 6 Learning Management System (LMS)
- CLIN 0005: Option 4E Integrating Tissue Hydration

The period of performance was 03 September 2013 to 25 September 2015. The program was completed within the allotted budget.

Airway model with sensors, computers and all pertinent instruction was delivered to the U.S. Army Research Laboratory (ARL) in September 2014. Instructions included wire connection instruction, computer operation and data retrieval. Validation study with additional prototypes was subsequently conducted with Dr. Christine Allen. Two additional airway models were shipped to ARL in March 2015 with physiological/pathology differences including burnt and swelling airway and recessed chin with facial hair airway.

The final demo for the Experiential Learning Management System (XLMS) and Tissue Hydration occurred Oct. 22, 2015 at the University of Minnesota. Shown in Figure 1 is a photograph of the review team which was comprised of ARL Cooperative Agreement Manager, Jack Norfleet, and the University of Minnesota CREST team members.

Figure 1: Photo of Review Team

3 Airway II Base Project

Processes and deliverables for the base project were discussed extensively in quarterly reports. An overview will be presented here.

Following clinical input from Anesthesia, Emergency Medicine and First Responders, the prototype from the Airway Part Task Trainer was redeveloped and improved. The focus was on the procedural steps involving physical interactions with the patient. Re-design changes included enhancing the tissue fidelity and durability of the tongue, and re-design of the cricothryrotomy skin puck. In response to feedback suggesting that we tighten the force to insert the endotracheal tube, we reduced the initial gap and strengthened the tissue. With the initial design, the epiglottis didn't pivot anteriorly with blade manipulation and it was too big. The epiglottis was redesigned by increasing the firmness of the epiglottis tissue and adjusting the mobility at the hyoepiglottic ligament so it can retract anteriorly with blade pressure on the vallecula. Mobility of the airway tissue under load of a laryngoscope was decreased to limit the collapse of the airway form when the laryngoscope was used to retract the tongue prior to intubation. Additional sensors were also implemented into the model as per Figure 2.

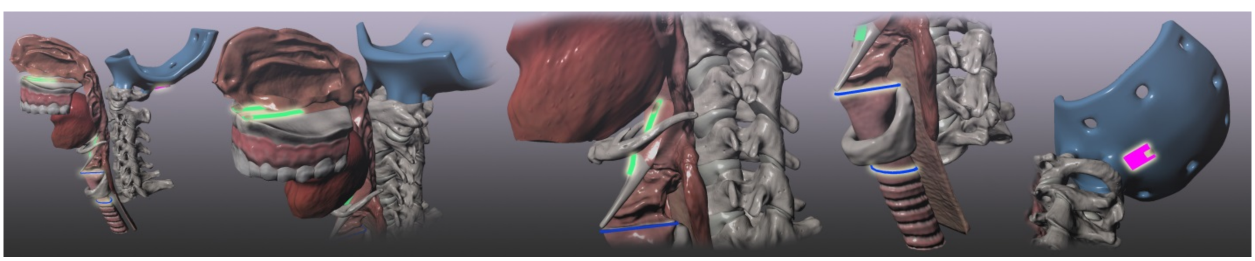


Figure 2: Sensor placement

Airway sensor placement

1. Top teeth
2. Upper palate
3. Epiglottis
4. Vocal cords
5. Intubation balloon pressure
6. Head inclination
7. Shoulder inclination

Figure 3: Skins, mouth assemblies and airway/sensor units for prototypes.

Figure 4: Completed skin with new neck plug

Figure 5: Airway Model with sensors, computer, key board and power supply ready for shipping.

4 CLIN 0002 and CLIN 0003 Options

Additional sensors for cricothyrotomy were incorporated into the prototypes as discussed above. The validation study was conducted with Dr. Christine Allen from ARL. Original and additional prototypes were used in a survey of military medical personnel and trainers at Joint Base Lewis McChord in Tacoma, Washington in November of 2014.

In response to the request for a representation of traumatic pathology, a burnt and swollen airway was created and delivered (Figure 6). We also delivered an example including some features of a difficult airway: a recessed chin with facial hair (Figure 7). These models and instructions for use were delivered to ARL in March of 2015. (Instructions attached in appendices).

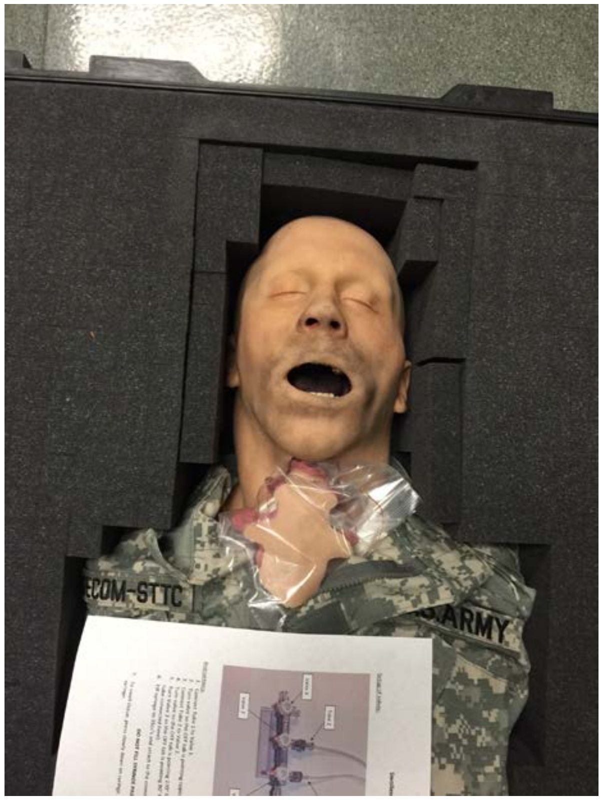


Figure 6: Burnt/swelling airway model with instructions

Figure 7: Recessed jaw/facial hair airway model

5 Highlights of Airway II Final Demo

Figure 8: Demo of XLMS

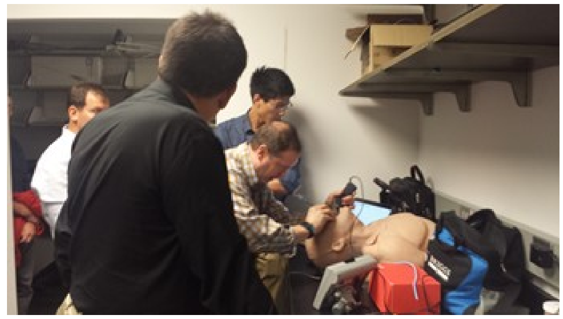


Figure 9: Demo of Tissue Hydration

The Experiential Learning Management System (XLMS) demonstrated the user interface for a learner and administrator. We also demonstrated the interface between the embedded sensors of the physical manikin airway and what a learner might see in real time (formative feedback) and as a final performance score (summative feedback). For the demo, standard interfaces and open source software were utilized. The demonstration showed how the student would utilize the XLMS to complete a lesson in intubation. The student logged into the XLMS, viewed lesson videos, received instructions, physically performed intubation on the manikin and was formatively and summatively scored by the XLMS. The results were recorded and we demonstrated play-back for the instructor.

In order to address the common problem of high friction force inherent in synthetic systems as they interact with instrumentation, the final demo for the tissue hydration model consisted of a fully implemented, automatic, low cost solution to addressing automated tissue surface coverage with liquid saliva. The unit was powered up, a motion sensor was activated, automatically primed, and the surface of the airway was coated via ducts in the side of the mouth, upper soft palate, and larynx addressing the sides and top of the tongue, and the epiglottis and vocal cords. The intubation was successful with adequate lubrication of the airway and the endotracheal tube.

The contractual requirements were met and further details on these options are discussed below.

6 CLIN 0004, Option 6 Learning Management System (LMS)

6.1 Objective of the LMS Effort:

One learning management system will be installed within the operational computer of the airway system, including a software installation that will integrate with the data acquisition platform.

6.2 Overview of Airway Experiential Learning Management System (XLMS)

Figure 10 provides an overview of the XLMS. The XLMS was loaded onto a standard laptop. The XLMS demonstrated the capability of interfacing between the airway sensors and the student user. It demonstrated how an instructor could create a curriculum, as well as add/subtract and monitor their students' progress. Included in the XLMS are data-bases containing force sensor outputs, lesson plans, and a scoring system with adjustable pass/fail criteria (placeholders exist now) and operating instructions. All interfaces are standardized.

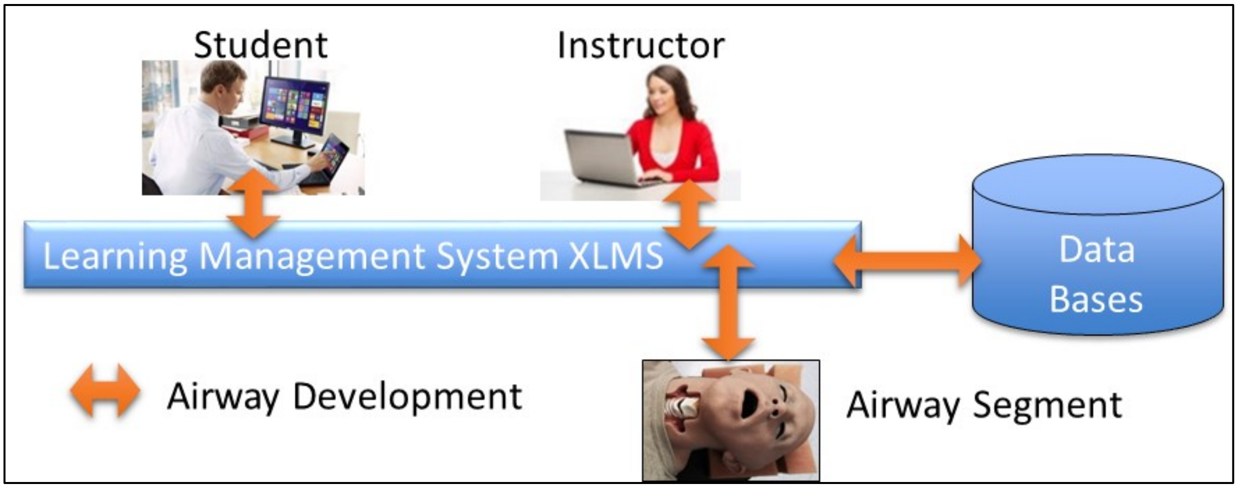


Figure 10: Overview of XLMS

6.3 Final Demonstration

Figure 11a shows the final demonstration to the Cooperative Agreement Manager, Jack Norfleet. A sample output of the airway sensors is shown in Figure 11b.

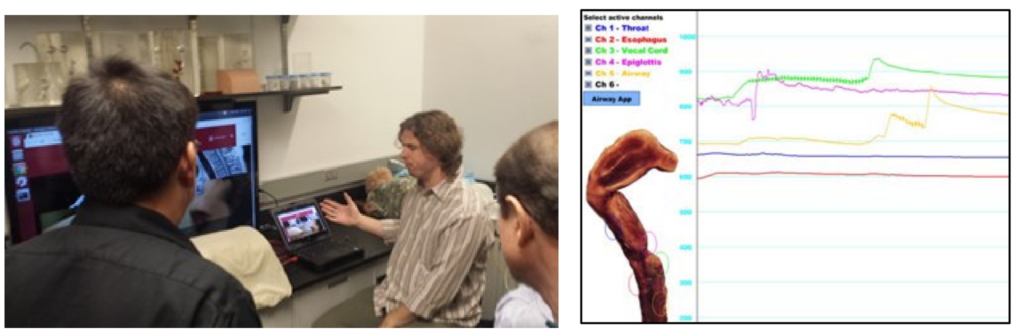


Figure 11 a,b: Demo of the XLMS

6.4 XLMS Architecture

The XLMS architecture is shown in Figure 12.

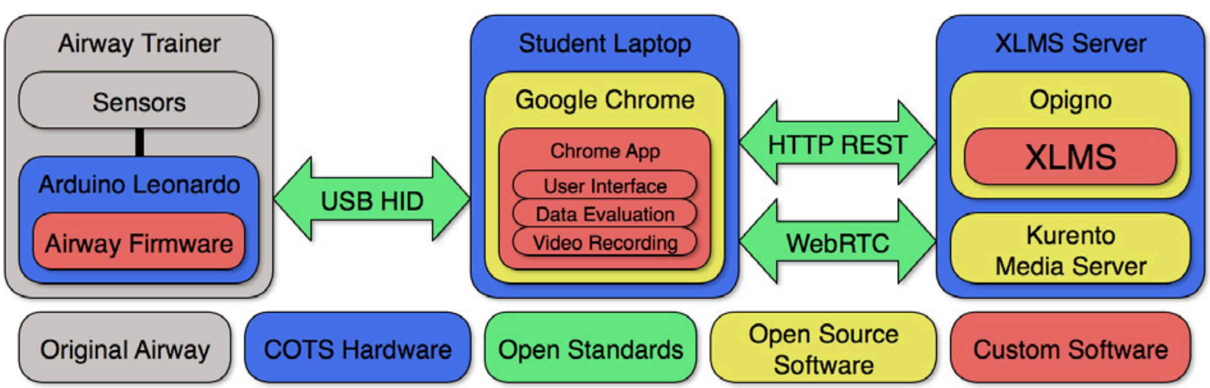


Figure 12: XLMS Architecture

This process of transforming raw sensor signal into student performance data required multiple steps. First, the raw signals were interpreted and transformed into data used to evaluate student performance. This transformation was done by the Airway Firmware on an Arduino Leonardo. The Airway Firmware transmitted the student's real-time performance data to the Chrome App, where it was recorded and then evaluated. Next, the Chrome App reported the performance data and evaluated results to the XLMS. Finally, the XLMS stored the results in its database and linked the data with the appropriate student. Additionally, the Chrome App streamed the performance video to the Kurento Media Server, which stored the video for later retrieval by the XLMS.

The Airway and the Chrome App communicated over USB HID standard. The Chrome App and the XLMS communicated over the HTTP REST open standard. The Chrome App streamed video to the Kurento Media Server via the WebRTC open standard.

6.4.1 XLMS Functionality

The XLMS was built with permissions to have "limited roles", and was built to function as the portal through which students access course content and training exercises, instructors review training exercise results and overall student performance and manage the whole XLMS. Drupal, the framework for which the XLMS was built upon enabled extensive customization and configuration, in both functionality and appearance.

We demonstrated logging in as a student taking a course created by the instructor. They proceeded through the course pages, reviewing the material provided and we demonstrated quiz questions testing their comprehension of the concepts of endotracheal intubation. After reviewing the course materials, the student navigated to the exercise portion of the course, where clicking the "Start lesson" button caused the Chrome App to launch. Once the student completed the exercise and closed the Chrome App, they returned to the XLMS. We demonstrated the ability to view past results and instructor evaluations as well as the ability to repeat the exercise, and review content available to them in the XLMS.

We logged in as an instructor and demonstrated the capability of creating and managing a course. The XLMS demonstrated the ability of an instructor to review videos of student performance and assess their students based on a provided grading rubric. Curriculum design was demonstrated including updating or modifying elements (quizzes, videos, etc.). We demonstrated the ability of an instructor to review past student performance both in aggregate and by individual exercises.

We demonstrated an "administrative role" as well. When logged in as an administrator, we demonstrated how one might configure and manage the whole of the XLMS. As an administrator, we were able to create more fine-grained roles and permissions to enable, for example, the creator of a course to prevent anyone else from modifying the course. Because Drupal includes an extensible and robust system for roles and permissions, the XLMS was able to leverage that system with no additional development. All instructions were built into the system and therefore, no instruction manual was provided.

6.4.2 Electronics Hardware and Firmware Architecture

The electronics and firmware architecture is shown in Figure 13. The USB Human Interface Device (HID) protocol was selected as the interface between the Airway and the student laptop because it enables communication without necessitating the creation of custom device drivers. This significantly reduced software development and maintenance costs while enabling device support on a wider variety of operating system platforms. To most easily leverage the USB HID protocol, the Arduino Leonardo was selected.

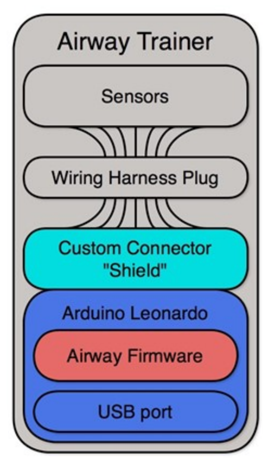


Figure 13: Electronics and Firmware

The microchip, around which the Arduino Leonardo was built, readily supported USB HID through the use of the open-source library LUFA. The microchip used on the Leonardo is widely available on other boards and as a stand-alone component and will therefore facility commercialization. In addition, the software required to develop firmware for these chips was provided free of charge from the manufacturer.

In order to connect the Arduino Leonardos to the existing wiring harness plug, and provide the needed resistors to properly condition the sensor signal, a custom printed circuit board (PCB) "shield" was created. It easily plugged into the Arduino Leonardo. The "shield" greatly simplified the effort required to connect the sensors to the Arduino.

While still in proof-of-concept and prototype development, the combination of the Arduino and "shield" provided the flexibility for rapid iteration at a low cost. It also showed promise as a robust solution that could withstand repeated demonstrations and travel.

6.5 Electronics

A new electronics controller was selected for the interface between the laptop and the airway. The new electronics interface consisted of an off-the-self Arduino brand micro controller, Leonardo model, and a custom circuit-board 'shield' to connect to the sensors. Shown in Figure 14a is a larger board 3” x 3”. A smaller board 1” X 2” is demonstrated in Figure 14b.

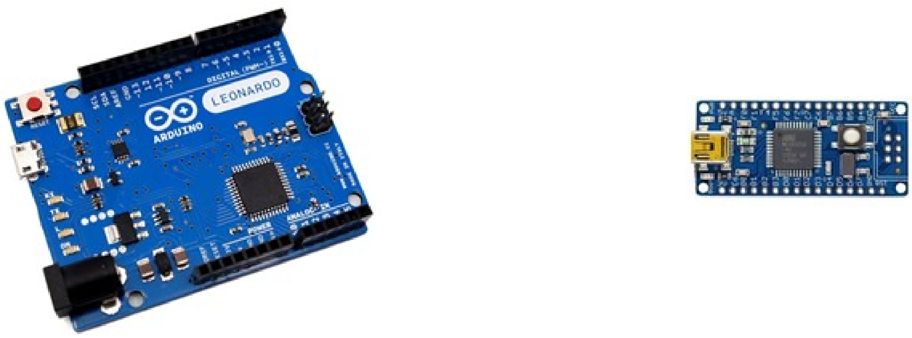


Figure 14a and b: Large and Small Arduino brand micro controller with USB interface

Functionally, the Arduino was able to read the sensor values, interpret them, and communicates via the USB HID standard to a laptop running the Chrome App described above in the XLMS.   Chrome was selected as it is a browser developed for every major OS platform.   USB HID was chosen as a universally-supported standard, assuring compatibility with nearly any commercially available computer.

The Dell Latitude 12 Rugged Extreme 7204 laptop is shown in Figure 15. This ruggedized laptop was delivered with the airway. The software on the laptop was completely self-contained, and required no outside connection (aside from the airway trainer, itself). It was connected to a centralized XLMS server that tracks multiple users on multiple trainers and collates their results in one location.

Figure 15: Ruggedized Laptop to Host XLMS.

The communication protocol used between the various components of the system was developed as an open standard. This will enable CREST to repurpose much of the software developed on this project for concurrent and future trainers, peripherals and modules.

6.6 Software and Communications Architecture

Shown in Figure 16 is an outline of the data-transfer between the XLMS, Chrome App and Airway Firmware over the course of one exercise.

To facilitate the transfer and evaluation of performance data from the Airway Firmware into student results in the XLMS, custom software needed to be created that could readily talk to both systems. Because the XLMS is accessed exclusively through a web browser, a browser platform was selected which provided easily accessible USB HID communication as well as cross-platform support. Google Chrome provided this by way of a specialized means of extending functionality called a Chrome App. Google Chrome's availability across all major PC operating system platforms as well as through low-cost Chromebook laptops was an attractive feature.

The custom Chrome App also provided an easy means of creating a sophisticated User Interface (UI) by using the same technologies used to create websites. The UI created for the Airway Trainer enabled the student to start and stop their exercise, while providing real-time feedback of their performance during the exercise, and the student's final performance score. Additionally, a second UI capably displayed the video feed being recorded for later evaluation by the instructor.

In order to properly configure the Airway and evaluate student performance according to parameters configured by the instructor, the Chrome App retrieved data from the XLMS upon being launched. The Chrome App was told where to retrieve information vis-à-vis the XLMS when it launches the Chrome App. The Chrome App was triggered when the student clicked the appropriate "Start lesson" button from the Google Chrome browser.

All communication between the Chrome App and the XLMS happened vis-a-vis the HTTP open web standard, using the widely practiced architectural pattern, REST. Support for HTTP REST in the XLMS was provided by an

open-source extension to the Drupal open-source framework. The data was serialized using the open standard JSON format.

Support for streaming video from the Chrome App was provided by the open-source project, Kurento Media Server. Kurento provided support for streaming video over the internet via the WebRTC open standard. Kurento also had its own open protocol for controlling the Kurento Media Server to properly handle media provided to it. Kurento combined several complicated technologies to enable easy access to create streaming video services, which is no small feat.

By leveraging existing free and open-source software, platforms, and protocols, the development time for the whole system was greatly reduced and the quality of software and functionality provided was far greater.

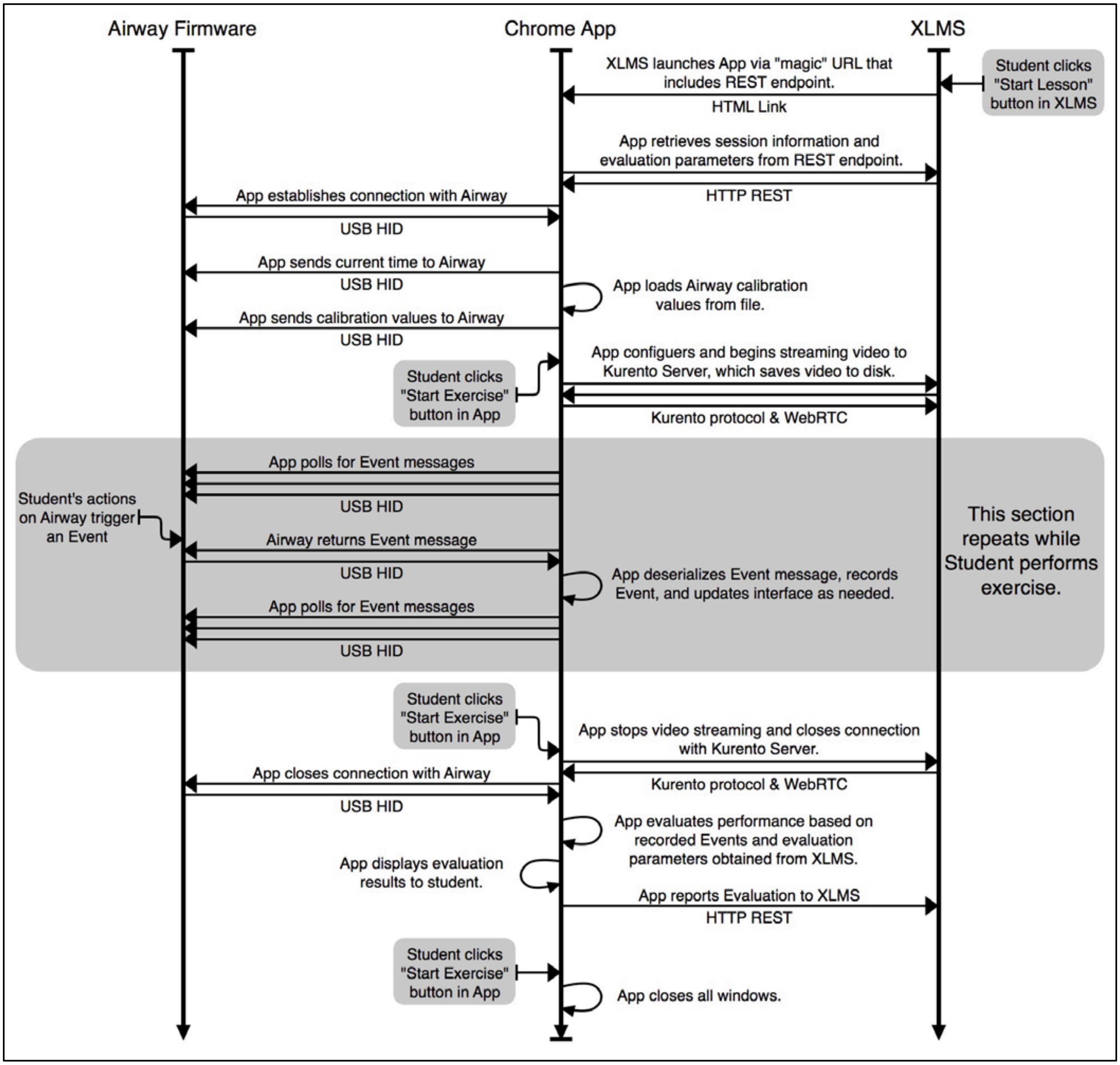


Figure 16: Outline of the data-transfer between the XLMS, Chrome App and Airway Firmware over the course of one exercise.

7 Airway CLIN 0005 Option 4E– Integrating Tissue Hydration

7.1 Objectives of Tissue Hydration Effort

The objective was to create a model that produces simulated saliva/mucous, in-line with the needs of the DoD. It was designed to provide a self-sustaining, continuously moist environment within the airway tract for endotracheal intubation. This was demonstrated as a stand-alone demo in a more robust, "commercialized", but sensorless version of our airway. The future development pathway will converge these efforts.

History: THE SALIVARY GLANDS The three major salivary glands (parotid, submandibular and sublingual) contribute to 90 percent of the mixed fluid in the mouth that is known as whole saliva; minor salivary glands that are scattered throughout the mouth contribute to the remaining 10 percent of the mixed fluid. Food debris, microorganisms and gingival crevicular fluid are other components of whole saliva. Saliva is composed of approximately 99 percent water and 1 percent proteins and salts. The normal daily production of saliva is between 0.5 and 1.5 liters. The submandibular glands are the major contributors to resting (unstimulated) saliva, and the parotid glands are the major contributors to stimulated saliva. The contribution of sublingual glands to unstimulated and stimulated whole saliva is low 5, 6 although the minor salivary glands are not major contributors to the whole-saliva volume, they play a significant role in the lubrication and protection of the oral mucosa because of their mucous secretions. Parotid gland secretion is purely serous, and submandibular and sublingual gland secretions are mixed (mucous and serous). The primary saliva, formed by the acinar cells, has an ionic composition similar to that of plasma. It is modified by the ductal cells to a hypotonic solution by reabsorption of sodium and chloride without water.

Approach: To test and research materials and methods that best suit creation of a mechanically lubricated environment within the oral cavity and to the larynx to facilitate the accurate frictional force and instrument interactions. This model will also address lubrication of the tissue in a manner that minimizes maintenance, cleaning, mold, or bacteria formation. Rapid iterations of variations will incorporate feedback from SMEs in Anesthesia, Emergency Medicine, ENT, and First Responders as well as Mechanical and Chemical Engineers.

Principles:

- Made in tandem with 7-Sigma's newest airway model
- Addresses DoD requirements from Needs Assessment Visits
  - Ease of cleaning
  - Maintenance of "wet" tissue
  - Automated method of applying lubrication
- Reliable
- Better than Pluck (pig, cow airway), and current manikins
- Material does not degrade tissue
- Can easily add blood, dirt, mucous variations
- Does not require a person to lube airway – automatic
- Clean out easily – water – air dry

7.2 Overview of Tissue Hydration Final Demo

A photograph of the final demo is shown in Figure 17. The final successful demo for the tissue hydration model consisted of a fully implemented, automatic, low cost solution to addressing automated tissue surface coverage with liquid saliva representative. The unit was powered up, motion sensor was activated, automatically primed, and the surface of the airway was coated via ducts in the side of the mouth, upper soft palate, and larynx addressing the sides and top of the tongue, and the epiglottis and vocal cords. The intubation was successful with adequate lubrication of the airway and endotracheal tube.

Figure 17: Demo of Tissue Hydration

7.3 Hydration Approach

The basic approach was to test and research materials and methods that best suit creation of a mechanically lubricated environment within the oral cavity and to the larynx to facilitate the accurate frictional force and instrument-tissue interactions. This model addressed lubrication of the tissue in a manner that minimized maintenance, cleaning, mold, or bacteria formation. Rapid iterations of variations incorporated feedback from SMEs in Anesthesia, Emergency Medicine, ENT, and First Responders as well as Mechanical and Chemical Engineers.

Hydration Progress - An overview of the progress and concept is shown in Figure 18. Preliminary concepts led to two approaches. These approaches, defined as "plumbing" and "surface coat", are compared in Figure 19.

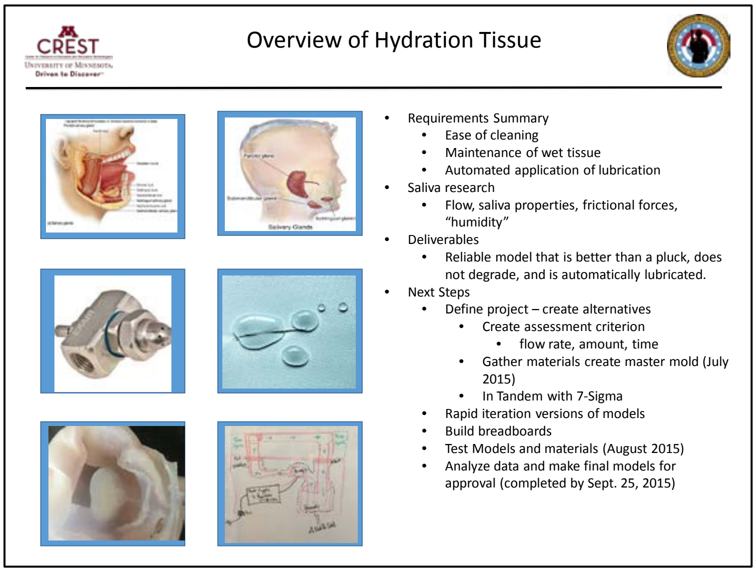


Figure 18: Overview of Hydration Concept and Progress

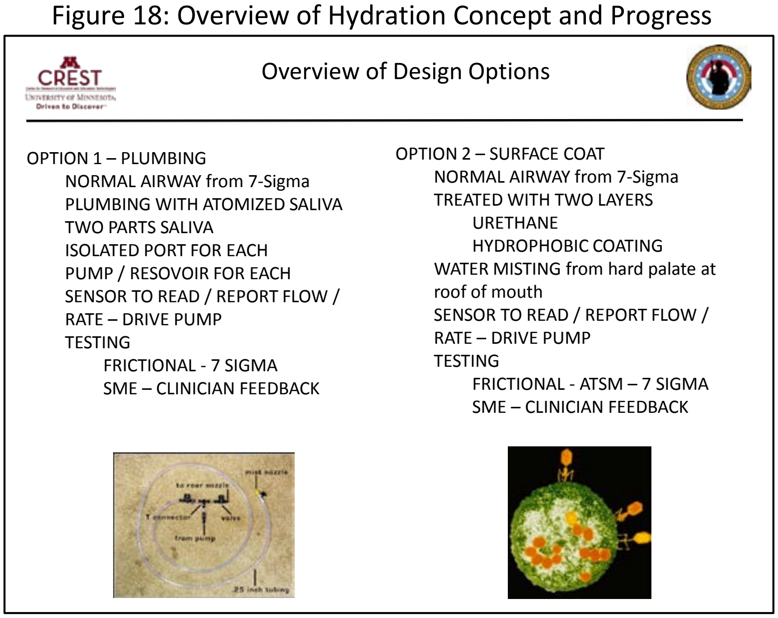


Figure 19: Overview of Design options.

A block diagram of the system is shown in Figure 20.

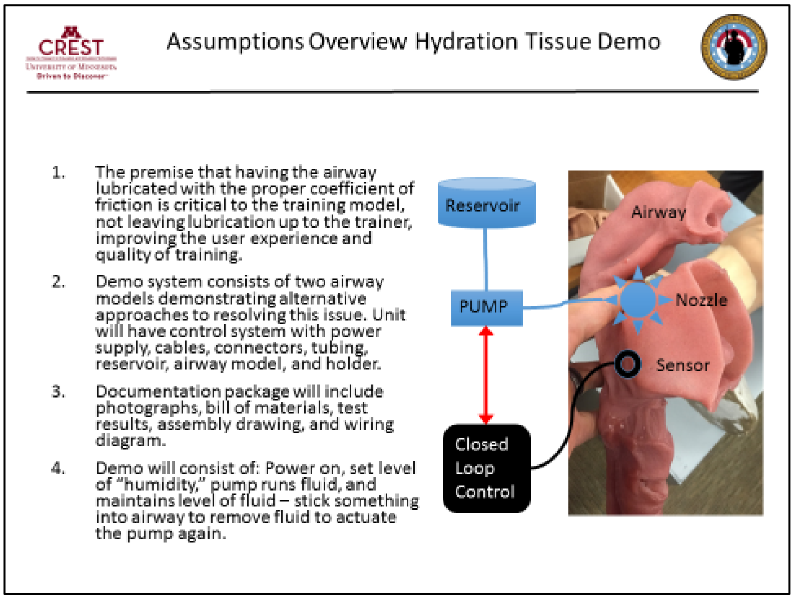


Figure 20: Block Diagram of Hydration system

To select the best approach for tissue hydration which includes pumps, nozzles, and coatings, a trade study was conducted and implemented successfully. The purchase and delivery of the test pumps, sensors, nozzles and motors was completed on time.

During the month of August 2015, it was determined that a current version of the torso and head could be supplied from 7- Sigma to be used when demonstrating the airway. The airway 7-Sigma model was completed, retrofitted, and tested. This model was held the airway, pump, fluid reservoir, and electronics. As a result of this effort, a feasibility study is being conducted by 7-Sigma for manufacturing and commercialization. Shown in Figure 21 is the 7-Sigma Airway head/airway/hydration system that will be delivered. Figure 22 shows the base airway model provided for retrofitting by 7-Sigma.

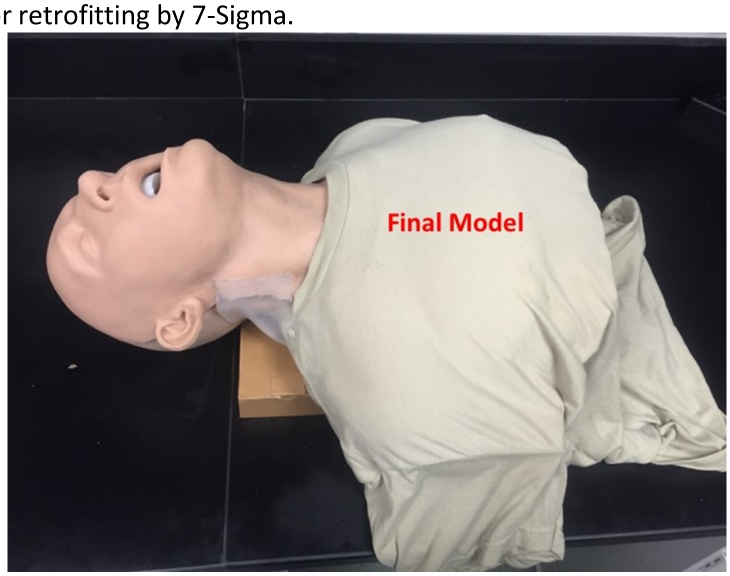


Figure 21: Final automated saliva airway model embedded within 7-Sigma torso

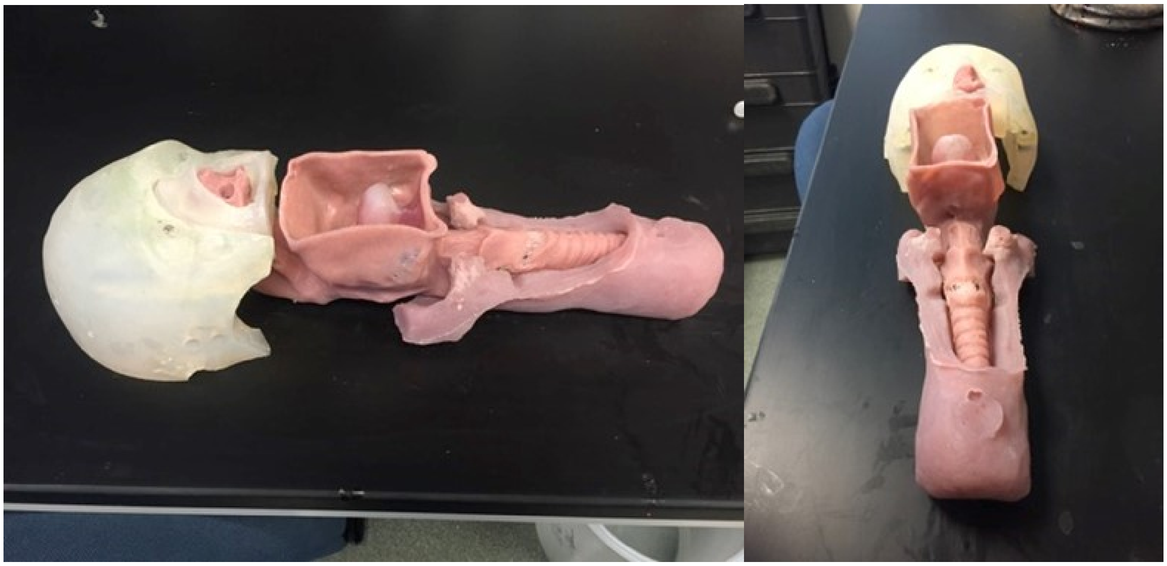


Figure 22: Base model provided for retrofitting by 7-Sigma

7.4 Analysis of Options:

Analysis of the approaches was completed to determine the optimum configuration based on location of emitters, type of emitters, sensing method, pumps, and reservoir. The results of this analysis are shown in Table 1.

Table 1 Matrix of test modules for development of most effective model.

Course of Action (COA)	Location of emitters	Type of emitter	Sensing	Pumps	Reservoir	Model	Frictional forces
1	In place of salivary ducts	Microvasculature tubing network to "pore" opening	1 - Airway sensors (7Sigma) 2 - Humidity Sensor – retro-naso-pharynx (Arduino sense) 3 – Motion Sensor (PIR), roof of mouth (Arduino sense)	Micro Fluid pump	1 – 16 oz reservoir kit 2 – 4.5 oz reservoir kit 3 – scooter brake reservoir 4 – closed pressurized reservoir kit 5 – Refill kit	Retrofitted 7 Sigma Silicone model with 1 sensor	Contact angle and coefficient of friction tests
2	Near salivary ducts	1-outlet manifold drip emitter		12V Fluid pump			
3	Optimum for coverage	9-outlet manifold drip emitter		12V spray pump (High pressure, low volume)			
4	Optimum for flow	Choice of what works best out of selection		12V variable control pump (Arduino controlled)			
5	Spray locations	Micro mist ultra fine misting nozzles		12V intermittent (Arduino controlled)			

6	Thin fluids locations	Choice of what works best out of selection		12V variable control pump (Arduino controlled)			
7	Thick fluid locations	Choice of what works best out of selection		12V variable control pump (Arduino controlled)			

7.5 Selection of Location of Emitters as Compared to Human Gland & Duct

The potential location of emitters that most accurately emulate humans was the objective of this study. To accomplish this objective the human anatomy and functions of actual salivary gland ducts were studied. The following criteria were considered locations for “emitter” placement in the airway.

1. In place of salivary glands
2. Near salivary glands
3. Optimized for saliva coverage
4. Optimized for flow
5. Spray locations
6. Thin fluid locations
7. Thick Fluid locations

The human gland and duct location relative to the airway are shown in Figure 23. This anatomy location helps to establish a starting point for evaluation of the nozzle locations.

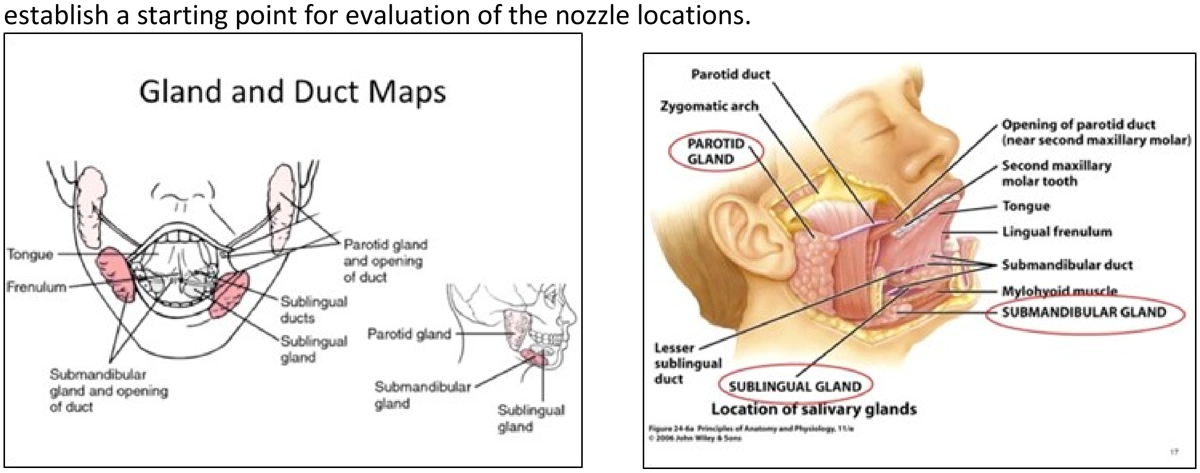


Figure 23: Human Glands and Ducts maps

Shown in Figure 24 is a comparison overlay between the human gland and duct locations and the proposed airway locations. This formed the starting point for designing the tissue hydration emitters. Based on this overlay the airway models were built for the emitter locations. This is shown in Figure 25.

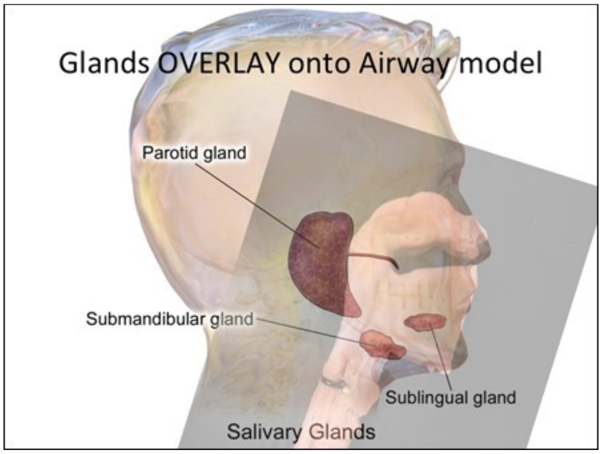


Figure 24: Overlay of glands onto 7Sigma silicone model - location options

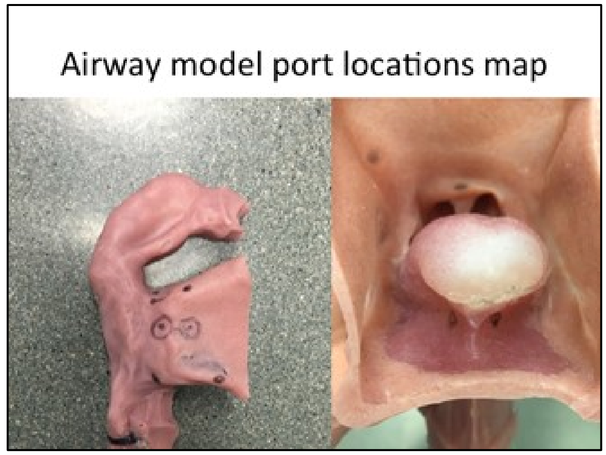


Figure 25: Airway model emitter & duct locations marked on model

7.6 Emitters / Duct options / Plumbing

7.6.1 Emitters

Four types of emitters were selected for evaluation based on the ability to drive water, and water based salivary solutions thorough the delivery tubing and airway surface coverage capabilities. These emitters are shown in Figure 26. All emitter types will be tested for efficacy and capability. The emitter selected was the Orbit ¼" misting nozzle shown on the far right. Shown in Figure 27 is the nozzle embedded into the airway. http://www.homedepot.com/p/Orbit-1-4-in-Portable-Outdoor-Cooling-Misting-System-20066/100373179.

Figure 26: Emitter head types based on capabilities for pressure and viscosity

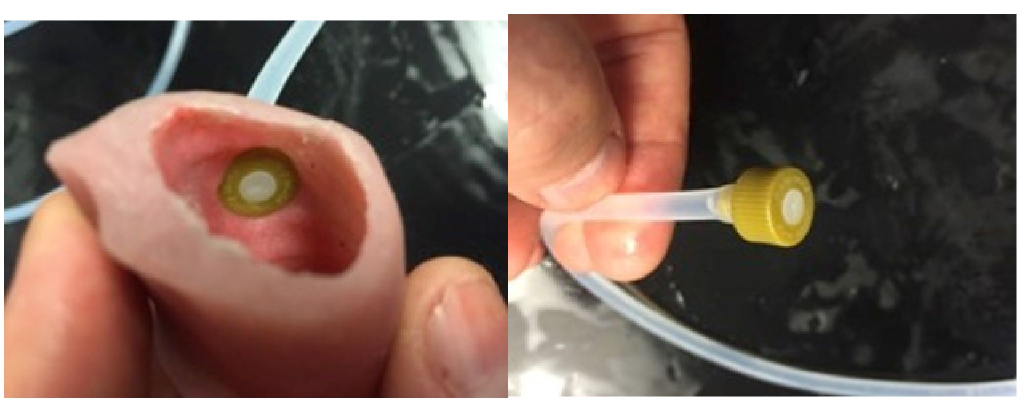


Figure 27: Test embedding emitters into model

7.6.2 Plumbing

Emitter plumbing was comprised of silicone tubing (3mm ID) and connected with 3/32” polypropylene tube to tube fittings (CPC Part #HS3, HE3, HT3, and HY3). Tuning connectors were secured with superglue and coated with waterproof adhesive. The tube connectors from CPC are shown in Figure 28.

TUBE TO TUBE

TUBE TO TUBE FITTINGS - STRAIGHT

PART NO.	DESCRIPTION
HS2	Polypropylene Straight Fitting with 1/16" Hose Barbs
HS230	White Nylon Straight Fitting with 1/16" Hose Barbs
HS231	Black Nylon Straight Fitting with 1/16" Hose Barbs
HS3	Polypropylene Straight Fitting with 3/32" Hose Barbs
HS330	White Nylon Straight Fitting with 3/32" Hose Barbs
HS331	Black Nylon Straight Fitting with 3/32" Hose Barbs
HS4	Polypropylene Straight Fitting with 1/8" Hose Barbs
HS430	White Nylon Straight Fitting with 1/8" Hose Barbs
HS431	Black Nylon Straight Fitting with 1/8" Hose Barbs

Figure 28: Tube connectors from CPC

Fluid tubing plumbing was created to best retrofit the airway and duct locations while allowing implementation into the head and torso holder, while maintaining functional movement, secure tubing, and ensuring that leakage would not occur. **In over 100 tests, we have had no leakage of the tubing this far.**

Figure 29 shows are the options for tubing size, and layout of implemented plumbing. The option on the left was chosen, with one exception. There was an additional port added to the middle top of the circuit to optimize flow, and keep circuit pressures even. Figure 30 shows the plumbing embedded within the airway model for testing.

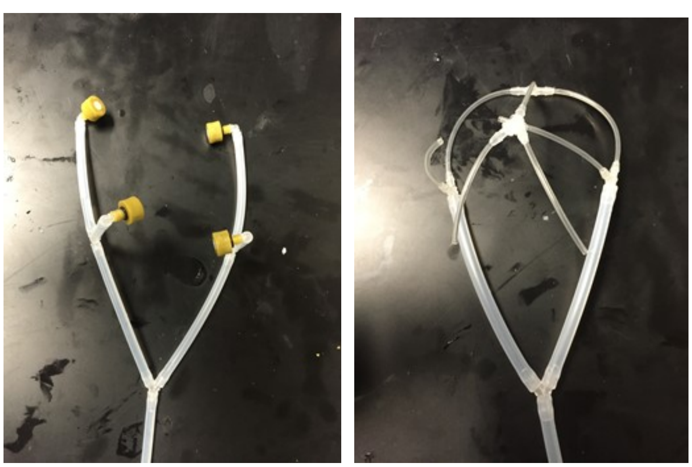


Figure 29: Plumbing options

Figure 30: Plumbing embedded within model for testing

7.7 Sensing Options:

Humidity sensors, PIR motion sensors, and 7-Sigma sensors were considered for integration into the system. Humidity sensors proved to be unsuitable and unreliable to use because our of the lack of airflow in our model, and therefore were not included in model testing.

Automaticity was achieved with the use of the PIR sensor placed at the roof of the mouth (hard palate) in combination with 7-Sigma conformable sensors serving as activators that initiate salivation in the airway. Intermittent application of lubrication was optimized by time-dependent Arduino-driven pump activation with volumes, frequency and characterization fine-tuned via clinical input.

Salivation was programmed to stop when the sensors reported no activity for 30 seconds. This is an adjustable parameter. Activation of lateral channels at the base of the tongue occurred as the endotracheal tube or laryngoscope passed across the oral cavity, creating a “misting” of the entire airway with either device.

PIR sensors were chosen so that they would not be affected by light, as they measure the infrared light that radiated from objects in the field of view.

Shown in Figure 31 are humidity sensors selected for evaluation and Figure 32 shows the PIR selected for evaluation.

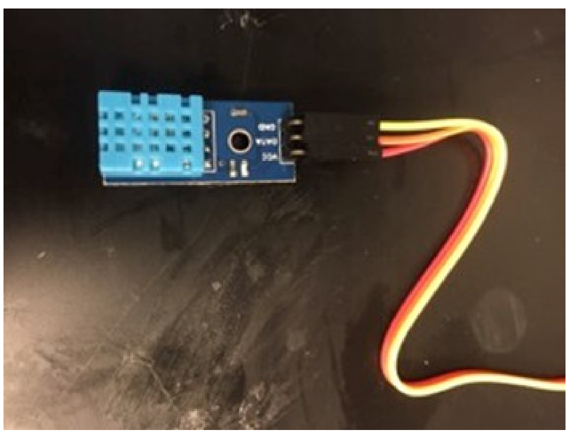


Figure 31: Humidity Sensor

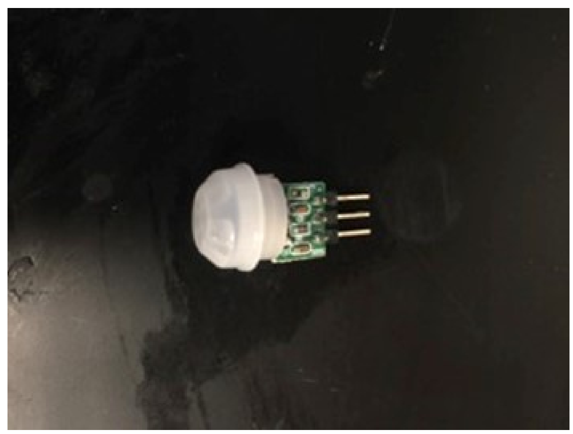


Figure 32: Passive IR Sensor

7.8 Implementation of Sensors

The PIR sensor was integrated into the hard palate just behind the teeth so as to optimize the field of view and reduce its obvious presence to the user. It was placed in an area that has the least chance of collision with instruments or other objects in the airway.

Figure 33 shows the upper hard palate outfitted with the PIR sensor. The electrical wiring and connectors were routed adjacent to the outside of the airway, and secured with superglue and covered in silicone for protection.

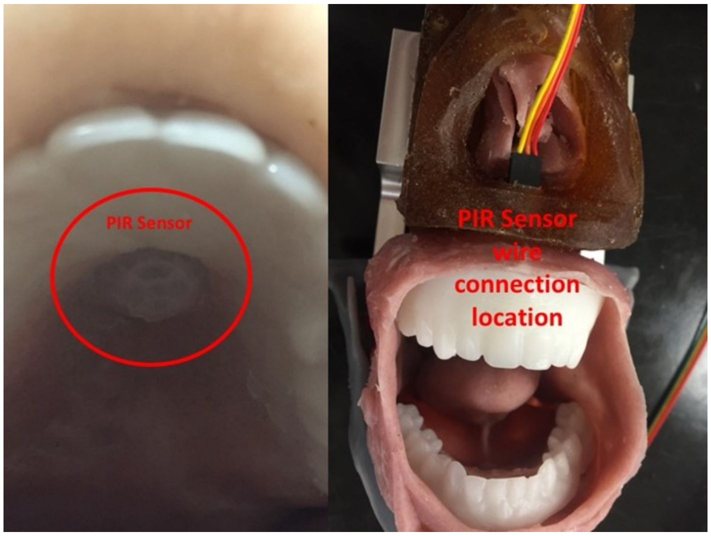


Figure 33: location and wiring of the PIR sensor

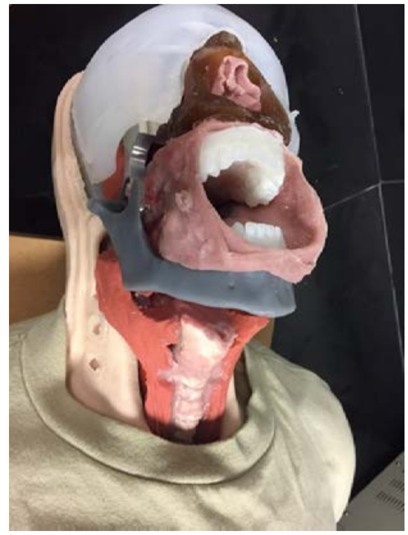


Figure 34: shows an inner-view of a model with embedded sensor, ducts, connectors, plumbing, and wiring, integrated into 7 Sigma head and torso.

7.9 Types of Pumps options:

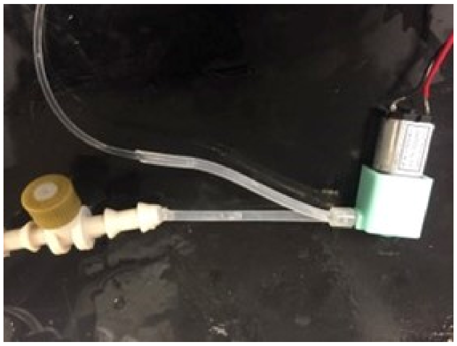
Three main pumps were tested for performance. These pumps are shown in Figure 35. They were chosen based on D/C current and amperage use, output / flow rate, sound while operating, size of tubing accommodated, and compatibility with Arduino programming. The performance characteristics for all 3 pumps are given in Table 2.

Further information on the pumps can be found at through the links provided below.

12V DC Peristaltic dosing pump head with connectors.
http://www.amazon.com/ZJchao-Peristaltic-Connector-Aquarium-Analytic/dp/B00F9MXFFQ

24V DC high flow (700ml/min) peristaltic pump.
http://www.kr4.us/Bartendro-Dispenser-Peristaltic-Pump-and-Controller.html?gclid=CjwKEAiAvauyBRDwuYf3qNyXmW4SJACX9-fXKmJU7ZnYB3hEf43q15zpATup3UQZnYzhj7uvaVe8xxoC04Hw_wcB

We did find that small air-driven misting pumps used for the automotive industry could have potential in delivering higher viscosity fluids with a small amount of air pressure.


Micro fluid pump,


12V Peristaltic dose pump

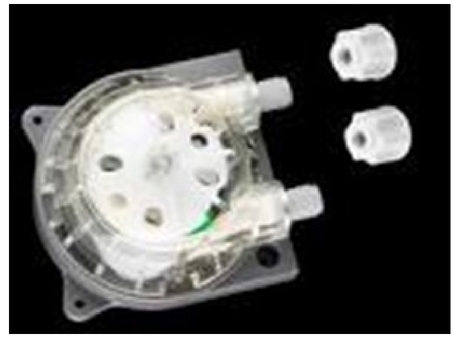

Bartendo pump

Figure 35: Pumps tested for flow and viscosity

Testing of the 3.5V Micro fluid pump revealed poor flow to generate misting from the nozzle. The 24V Bartendo pump required excessive power, was loud, and tubing diameter was large. The obvious choice for this version was the 12V peristaltic dosing pump.

	Micro Pump	**Peristaltic Pump**	**Bartendo Pump**
D/C Current use (V)	3.5	12	12 – 24
Amperage use	100mA	300mA	500mA
Flow / rate	120L/Hr	5000 RPM / 100 mL/ min	700 mL/min
Sound while operating	High pitched squeal of motor	Quietest design, click for activation	Low hum, but squeal when tubing is under pressure
Tubing Size	3mm	4.7mm	7.94mm
Compatible / Arduino	NO	Yes	Yes

Table 2: Table of pump capabilities

7.10 Fluid System Mounting In Manikin

Shown in Figure 36 is the fluid system connected to the manikin torso with plumbing lines routed to the airway.

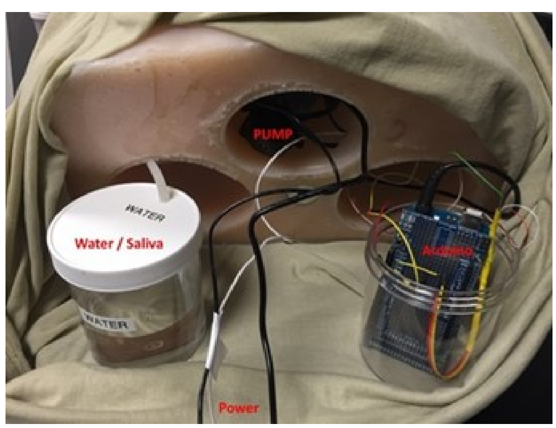


Figure 36: Complete setup with water reservoir

7.11 Adherence testing of hydrophilic coatings.

Tests were conducted to determine the adherence of hydrophilic coatings to the airway walls in an effort to reduce friction and better match the human airway friction forces encountered.

Ure-Bond II and Sil-Poxy (Smooth-On, Inc.) were trialed on samples of platinum silicone and urethane combinations with hydrophilic coatings of Zinc and Titanium/Silicone Dioxide (OxiTitan), cured for 24 hours and then hand pulled apart and visually inspected for delamination. None of the materials were able to sustain any amount of "pulling," and most had no adhesion at all. Please see Table 3 for a show of the testing results, and Figures 37 and 38 for test plate image and delamination examples.

Uses of urethane based hydrophilic materials are quite common in the medical device industry to decrease surface friction between devices and human tissues, specifically for catheters and introducers. None of the materials tested could provide protection against de-lamination at this time, therefore adhesion testing of urethane bases with silicone models provides quite difficult and not promising at this point. Further work to incorporate the two, or utilize a silicone based hydrophilic coating should be pursued.

Ure-Bond / Sil-Poxy	Urethane + Hydrophilic coating	Urethane Foam + Hydrophilic coating	Platinum Silicone + Hydrophilic coating	Tin Silicone + hydrophilic coating
Urethane	Some / None	Some / None	None / None	None / None
Urethane Foam	Some / None	Some / None	None / None	None / None
Platinum Silicone	None / None	None / None	None / None	None / None
Tin Silicone	None / None	None / None	None / None	None / None

Table 3 - Table of adherence testing - all models failed

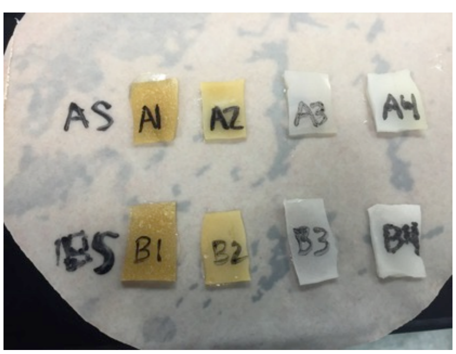


Figure 37: Adhesion testing plate (silicone example)

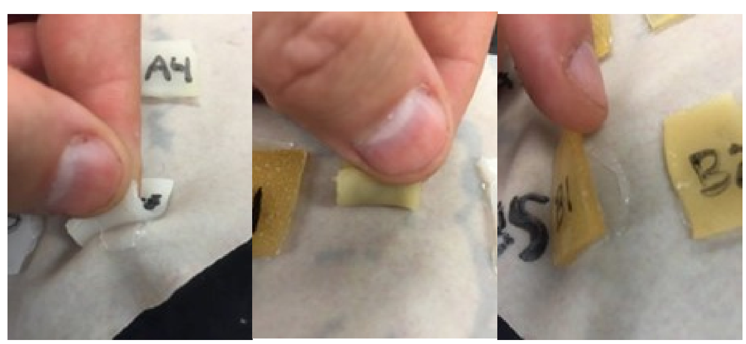


Figure 38: Examples of delamination and lack of adhesion

7.12 Airway Friction Testing

The testing plan was taken from Lauren Poniatowski (Masters / MD student in our program), who previously validated this method using human ureter and flexible scopes. Modifications were made to incorporate an artificial saliva recipe previously provided, COTS silicone spray, and water layer between sample and surface.

Base materials tested for coefficient of friction included Platsil Gel 10, Gel 00 (Polytek), Vytaflex 10 (Smooth-On), PC10/12 (BJB Enterprises), with 30-50% Smith's Prosthetic Deadener (Polytek), and/or 30-50% Siicone Oil (MPFX). Coatings included OxiTitan and Fine-L-Kote conformal coatings sprayed atop the surface of the materials or mixed <5% TVBW).

Determination of Coefficient of Friction: The coefficient of friction between two materials is defined by the equation:

$$F = \mu N$$

F is the force applied parallel to the material surfaces. N is the force perpendicular to the material surfaces. μ is the coefficient of friction and is dimensionless. μ is defined as the kinetic coefficient of friction when the forces are measured when the materials are actively sliding against each other. μ is defined as the static coefficient of friction when the force is measured when the materials are not moving relative to each other. The coefficient of friction was measured between synthetic material samples and one 1KG weight. The coefficient of friction was also determined from literature search for human tongue tissue.

The set up for measuring the coefficient of friction consisted of placing the tissue on an alcohol cleaned metal base surface of the Autograph Tensile test machine (Shimadzu, Universal Tester). Then 1cc of fluid "saliva" was added to the surface of the sample. The metal slide base was secured to the top of the tissues with double stick tape, and a 1KG circular weight was placed atop the slide base. See Figure 39 below for setup diagram. 14 Samples were tested each 3x for each "saliva" (water, silicone spray, and CREST Saliva). The test was started at a rate of 50mm/min and ran for 30 mm, or 30 seconds unless buckling of the materials occurred (2x). The force obtained from the load cell on the test machine was used as *F* and the force of gravity (-9.8m/s2) was used as N as it was perpendicular to the surface of the material. Results are summarized in Figure 38 below.

Tissue	Coefficient of Friction (μ)
Human Tongue	**0.25**
Base Silicone Only	1.52
Base Silicone + Water	1.32
"Cam" Silicone only	2.53
"Cam" Silicone + Water	**0.49**
Urethane only	1.35
Urethane + Water	**0.12**
Any silicone + Silicone spray	0.009
Any urethane + silicone spray	0.001

Figure 39: Coefficients of Friction and Tensile Test machine

7.13 Comparison of Tissue Hydration Techniques and Results

Determination was made that silicone oil based sprays provided excessive reduction of frictional interactions between surfaces of the tissues and instruments. This correlated to inaccurate interactions between instruments and physical models during training.

The silicone + hydrophilic additive models hydrated with water, performed within 2% of the coefficient of friction of human tissue, and urethane + hydrophilic additive models hydrated with water, performed within 0.5% of the coefficient of friction of human tissue. CREST Silicone recipes hydrated with water performed within 10% of the coefficient of friction of human tissue. CREST Urethane recipes hydrated with water performed within 6% of the coefficient of friction of human tissue. Anecdotal evidence from clinicians indicated a preference (in priority) for the materials + hydrophilic additives hydrated with water, then materials hydrated with CREST saliva, then materials hydrated with water. Due to the cost, maintenance, viscosity, and availability of resources, we recommend using water in our system until further research can provide a method to deliver higher viscosity fluids. A small amount of OxiTitan was tested as an additive to the water to provide anti-bacterial, anti-fungal, and anti-microbial growth within the models without affecting viscosity of the fluid.

For these reasons, all previous CREST Silicone and Urethane models were good options for creating airway training models. Further accuracy of the collision interactions can be attained with the addition of hydrophilic additives.

Future efforts should be focused on examining adhesives, silicone compatible hydrophilic coatings, and optical properties of urethane models.

Further testing should also be done to compare existing polymers used in COTS models, using cadaveric tissues as a reference (ARL/CREST Tissue Characterization project).

7.14 Electrical and Software

The electrical schematics are given in Appendix A. The software code for tissue hydration is given in Appendix B

7.15 Operating Instructions

- Plug in power supply, turn on, turn to 10V, turn off, plug into power strip
- Plug in Arduino power supply cord into power strip
- Fill water reservoir with clean water
- Turn on power strip
- Insert objects into mouth to prime system

7.16 Summary of Tissue Hydration

The requirements of the contract were successfully met. The compliance to the contractual requirements is stated below.

CLIN 0005, 6 months
Option 4E– Integrating Tissue Hydration
UMN Plan

- ✓ UMN will research the feasibility of a self-lubricating system.

- ✓ UMN will research and develop a self-contained airway and oral cavity module operating in high and low flow modes to hydrate tissue.
- ✓ UMN will design airway and oral cavity modules to integrate and connect tissue hydration.

ARL Plan

- ✓ ARL will assist and review the self-lubricating system.
- ✓ ARL will assist with integration and system ease of use.

Deliverable:

- ✓ UMN personnel will deliver units, two airway modules to integrate secretion capabilities. Including, but not limited to reservoir, pump, and electronics to interface to the computing system. (Waiting for direction from ARL when to ship units).
- ✓ UMN will set-up and train ARL as to its use.
- ✓ Requirement met

7.17 Recommendations:

Recommendations for follow on work in priority of ease to implement and cost to execute.

- **IR / UV indicator – contamination**
- **Sensor for flow/ rate – independent of physiology**
- **Tissue Temp normal, heated fluid**
- **MRSA / VRE / pneumonia / TB indicator**
- **Provides accurate odor**
- **Heated tissue, heated fluids**
- **Two-part fluid**

7.18 Measures of success:

This project met all measures for success in the basic category, and many of the items for the intermediate and advanced categories. Criteria met have been bolded.

Basic: The model is able to meet the above criterion for fluid flow, rate, and automaticity. It addresses cleanliness, bacterial/fungal growth, and rinse method is defined.

- **Low power**
- **Provides adequate frictional interaction with laryngoscope blade**
- **One-part fluid**
- **Rugged**
- **Oral cavity only**
- **Normal tissue temperature**
- **Easy to refill**

Intermediate:

- **Can be used with any model**
- **Trauma or recessed jaw stays the same**
- **Easy to incorporate into 7 Sigma model**
- **Fluid rate is sufficient for continuous use**
- Two-part fluid
- **Provides accurate color**
- **Rugged and feels correct**
- **Oral cavity and larynx**
- Sensor for flow/ rate – independent of physiology

o Tissue Temp normal, heated fluid
o **Easy to refill**
o IR / UV indicator – contamination

Advanced:

o **Provides gurgling sounds for breathing**
o **Provides bloody coagulated airway**
o **Provides CNV / CNI model cue for cric**
o **Provides accurate odor**
o **Ruggedness not an issue, feels, looks right**
o **Oral**, nasal**, and larynx cavities**
o Heated tissue, heated fluids
o **Easy to refill**
o MRSA / VRE / pneumonia / TB indicator

8 Summary of Expenditures

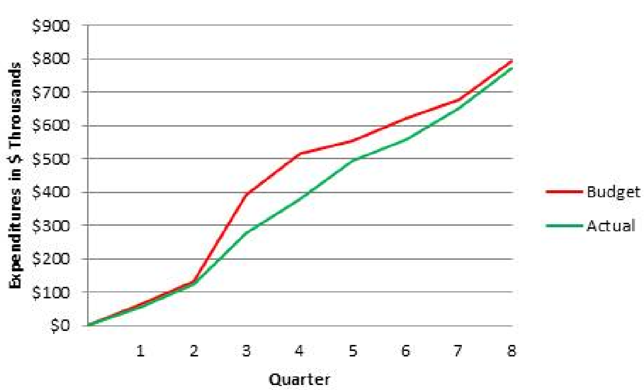
The program was completed within the allotted budget as shown in Figure 40.

Development of a Modular, Provider Customized Airway Trainer (Airway II)

Cooperative Research Agreement
Award # W911NF-13-2-0033

Period of Performance: 19 Sep 2013 – 25 Sep 2015

Cost Account	Cumulative Expenditure	Total Budget	Remarks
Personnel	$256,071	$190,896	Rebudget from professional services
Fringe Benefits	$75,620	$61,788	Rebudget from professional services
Travel	$10,935	$17,400	
Equipment	$0	$0	
Supplies	$93,585	$104,244	
Other (Services)	$78,774	$148,825	Rebudget to salary and fringe
Subtotal	$514,985	$523,153	
Indirect Costs	$258,399	$270,756	
Total	**$773,384**	**$793,909**	



Overall expenditures were slightly below budget. Expenditures for personnel (salary and fringe) exceeded amounts originally budgeted. Funds originally budgeted for professional services were rebudgeted for University personnel to do development and coding for the learning management system.

Figure 40: Financial Summary of the Program

Appendix A: Instructions for Airway Model with sensors and computer (Raspberry PI)

RASPBERRY PI INSTRUCTIONS

1. Connect multicolor sensor cable and two blue sensor cables (blue sensor cable orientation does not matter)

2. Plug in power to the screen and raspberry pi(two separate plugs)
    a. Systems turns on automatically (if screen does not come on, power down computer by unplugging it and reconnect to power)

3. Turn on keyboard (slide button on side)

4. Wait for login prompt

5. Login: pi
   Password: raspberry (password does not show up on the screen, TYPE CAREFULLY)

6. After login type "startx" and press enter. This will get you to the desk top

7. Double click on the LXTerminal icon on the desktop
    a. This is the terminal through which the program is run

Once in the terminal

1. Press the up arrow key till the "cd Adafruit_ADS1x15" command is reached; press enter

2. Once the directory is changed, press the up arrow key till the "sudo python 1115ADC_test.py" command is reached; press enter

3. Once program is started enter 30 for the first frequency (sampling frequency; press enter

4. Enter 250 for the second frequency (system speed); press enter

5. Enter time (in seconds) for program run and press enter to start the data collection (ensure you enter enough time for such interventions such as intubation as this can take people 1-3 minutes)

6. Once program is completed the data is stored as a text file

7. To collect more data repeat steps 3-7

8. Type exit and press enter to exit the terminal. This will bring you back to the desktop

IF WRONG COMMAND IS ENTERED, PRESS Ctrl-Shift-Q to exit terminal at any point

9. To turn off system double click on the Shut Down icon on the desktop and click – Yes

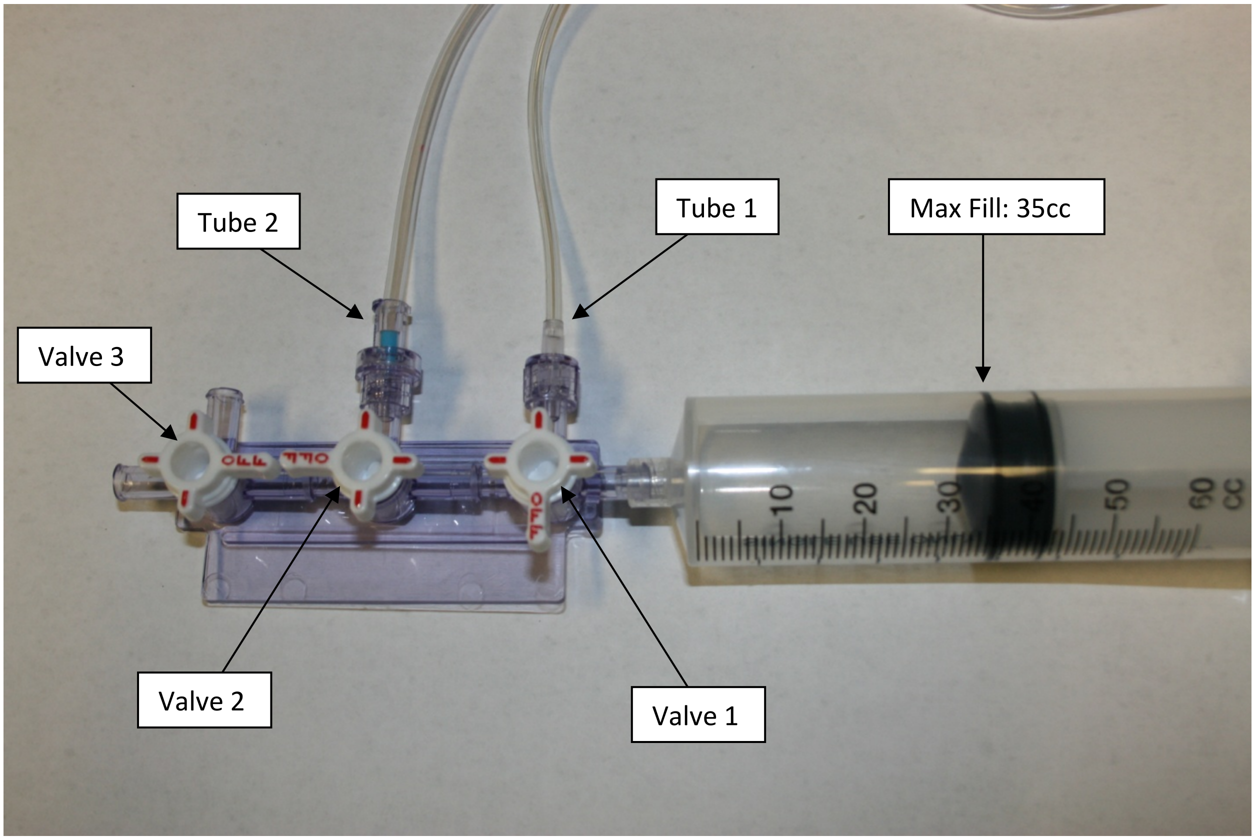
10. Turn off keyboard. Ensure keyboard is charged using the black USB cable

Accessing the data files

1. Click on the icon 2nd to the left in the task bar; this opens the file manager
2. Click on the icon labelled pi on the left hand column of the file manager
3. Proceed onto the Adafruit_ADS1x15 folder
4. All data files are stored in this folder
5. Data files are named as output14xxxxxx.txt
    a. They are named on the basis of the system time, therefore each data file saved will have a number associated with it as greater than the previously saved file

Appendix B: Instructions for Swollen Tissue

Setup of valves:



Instructions:

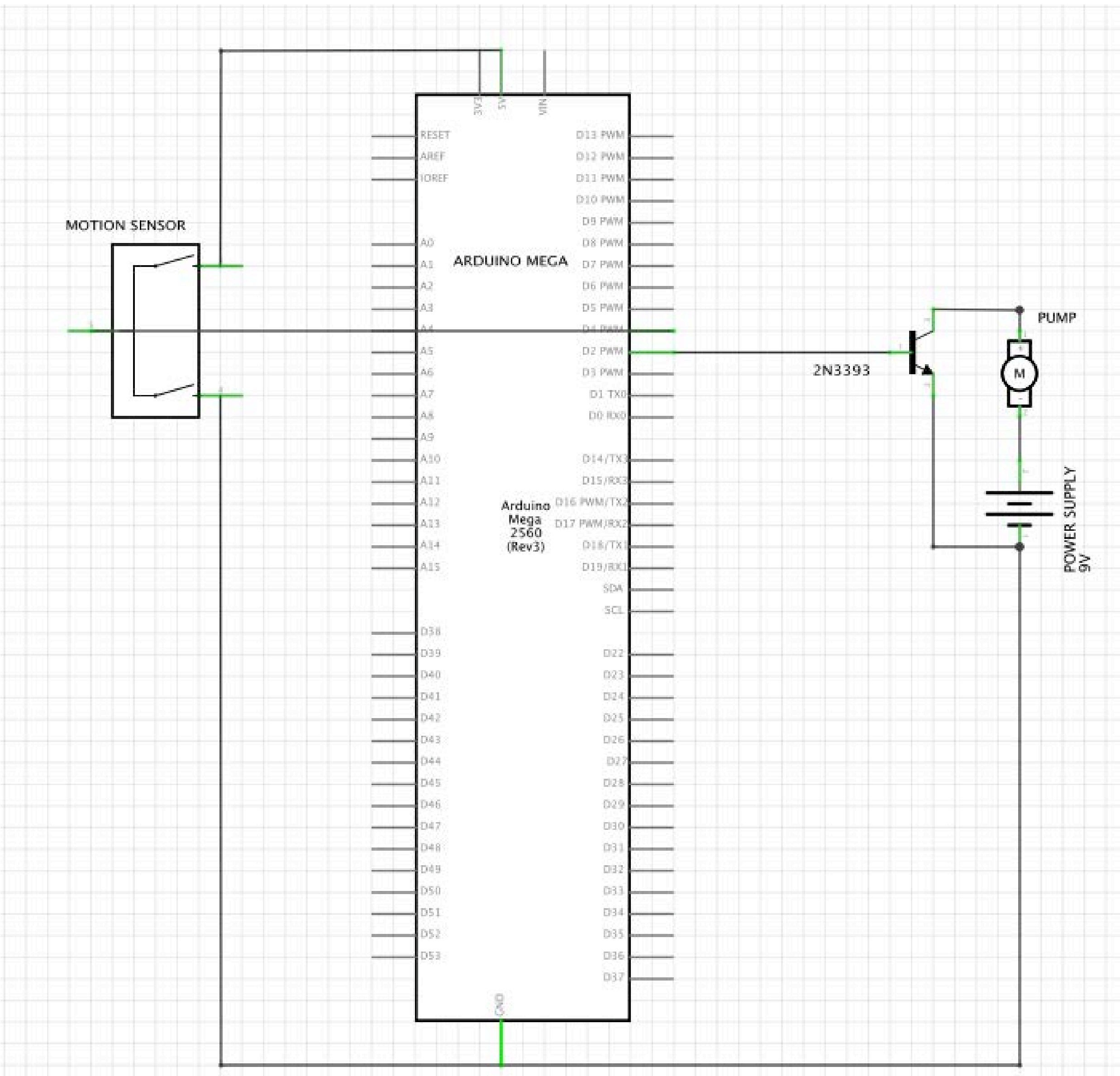
1. Connect Tube 1 to Valve 1.
2. Turn valve so the OFF tab is pointing opposite the tube connection.
3. Connect Tube 2 to Valve 2.
4. Turn valve so the OFF tab is pointing 270° from the tube connection.
5. Turn Valve 3 so the OFF tab is pointing 90° from tube connection (there will be no tube connected here).
6. Fill syringe to 35cc's and attach to the connection closest to Valve 1.

DO NOT FILL SYRINGE PAST 35cc's

7. To swell tissue, press slowly down on syringe. To deflate tissue, pull back slowly on syringe.

Appendix C: Electrical Schematics for Tissue Hydration

Motion sensor
Arduino Mega
Pump
Power supply



Appendix D: Software Code for Tissue Hydration

```
int pump = 2;                // pin to control pump
int pirSensor = 4;           // pin for PIR sensor
bool pirState = HIGH;        // controls state of pump--initial or maintenance
int val = 0;                 // variable for reading the pin status
double time0 = millis();     // variable to store test time
double  time1=millis();      // variable to store maintenance times
int testStart=0;             // variable to save test status (0=end, 1=start)

void setup() {
 pinMode(pump, OUTPUT);
 pinMode(pirSensor, INPUT);
 Serial.begin(9600);
}

void loop(){
   val = digitalRead(pirSensor);  // read input value
   Serial.println(val);
   if(val==1 && testStart==0){   //checking if sensor triggered and the test is not started
     pirState=HIGH;
     testStart=1;            // test started
   }
   initialPumpRun();         // intialpump run
   //Serial.println(millis()-time0);
   maintenance();            // maintenance runs of the pump
   if(millis()-time0>=30000){
     time0=millis();         //resetting test time
     time1=millis();
     testStart=0;            // test ends after 30 seconds
     //pirState=HIGH;
   }
}

void initialPumpRun(){
 if(testStart==1 && pirState==HIGH){
   time0=millis();
   digitalWrite(pump, HIGH);
   delay(1000);              // pump runs for 1 second
   digitalWrite(pump, LOW);
   time1=millis();
   pirState=LOW;             // initial pump run over
 }
}
void maintenance(){
 if(millis()-time1>=10000 && testStart==1){   // time between maintenance runs is 10 seconds
   digitalWrite(pump, HIGH);
   delay(1000);
   digitalWrite(pump, LOW);              // pump runs for 1 second
   time1=millis();
 }
}
```